

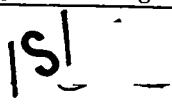
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20665/S004

CHEMISTRY REVIEW(S)

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CHEMIST'S REVIEW		1. ORGANIZATION HFD-810/110	2. NDA Number 20-665
3. Name and Address of Applicant (City & State) Novartis Pharmaceutical Corporation 59 Route 10 East Hanover, NJ 07936-1080			Supplement Date of Letter Number SLR-004 October 16, 1998
5. Drug Name Diovan®	6. Nonproprietary Name valsartan		7. Amendments & Other (reports, etc) - Dates none
8. Supplement Provides For inclusion of Post Marketing Experience subsection in the labeling, per our letter dated May 8, 1998.			
9. Pharmacological Category treatment of hypertension	10. How Dispensed Rx X OTC		11. Related IND(s)/ NDA(s)/DMF(s) none
12. Dosage Form capsule	13. Potency(ies) 80 and 160 mg		
14. Chemical Name and Structure			15. Records/Reports Current Yes X No Reviewed Yes X No
16. Comments There are no chemistry issues with this type of change. Some minor formatting changes were made that are acceptable.			
17. Conclusions and Recommendations We recommend that this supplement be approved in regard to chemistry.			
18. REVIEWER			
Name Carl J. Berninger, Ph.D.		Signature 	Date Completed November 9, 1998
Distribution: Original Jacket x Reviewer x Division File x PM x			
CJB File Name c:\sup-rev\20665s04.doc		R/D init: K. Srinivasachar	

11-12-98